



ORGANISATION FOR ECONOMIC
CO-OPERATION AND DEVELOPMENT

ENVIRONMENT DIRECTORATE
Environment, Health and Safety Division

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Paris, 18 December 2008

To: Working Group of National Co-ordinators of the Test Guidelines Programme (WNT)

**SUBJECT: THE BCOP AND ICE TEST GUIDELINES ON OCULAR CORROSIVES AND SEVERE IRRITANTS
FOR COMMENTS**

Dear Madam/Sir,

Please find attached the two draft Test Guidelines on “The Isolated Chicken Eye (ICE) Test Method” and “The Bovine Corneal Opacity and Permeability (BCOP) Test Method”, for your consideration. The draft Test Guidelines have been out once for comments earlier this year and the comments received were thoroughly considered by the Expert Consultation Meeting held at US EPA in Washington DC on December 4-5, 2008. The meeting agreed on a number of amendments in accordance with the comments received, including the inclusion of detailed Proficiency Standards. However, these will not be available until early February 2009 after which they will be included into the draft Test Guidelines, who will then be submitted to the WNT21 for provisional approval only. In addition, the expert meeting recommended that the draft Guidance Document on Ocular Histopathology, that has been prepared by US-ICCVAM, should be broadened and also include other aspects of Ocular *In Vitro* Testing.

The ICE and BCOP test methods are *in vitro* tests that can be used, under certain circumstances and with specific limitations, to classify substances as ocular corrosives and severe irritants as defined by the US EPA, the EU and the UN GHS. At this stage, the test methods cannot be used as full replacements for the rabbit *in vivo* test (Test Guideline 405). However, due to the low levels of false positives demonstrated by the validation studies, substances that are tested positive can be classified as ocular corrosives or severe irritants without further testing in rabbits. Chemicals testing negative would have to require further testing, using the TG 405 and the sequential testing strategy.

The draft Test Guidelines will be available on the public Website:

http://www.oecd.org/document/55/0,3343,en_2649_34377_2349687_1_1_1_1,00.html#Draft_TG_for_Comment

The compilation of comments with the expert meeting responses together with the draft Test Guidelines in tracked changes mode will be available on the protected Website, under “Draft Test Guidelines and Guidance Documents”. The meeting report from the December meeting in Washington DC will be available shortly under the section “Expert Meetings”:

[http://webdomino1.oecd.org/comnet/env/wg-nctg.nsf/viewHtml/htm/\\$FILE/index.htm](http://webdomino1.oecd.org/comnet/env/wg-nctg.nsf/viewHtml/htm/$FILE/index.htm)

User name <<toxicity>> Password <<testing>>



I would thereby like to invite National Co-ordinators to review the ICE and BCOP draft Test Guidelines. Your comments are requested **by the very latest 6 February 2009**, and if no comments are received the Secretariat considers this as silent approval to the present drafts. For the Secretariat to be able to respond to the comments received in a timely manner and prepare the draft Test Guidelines for provisional approval at the WNT21, it is crucial that this deadline is met.

Please don't hesitate to contact me if you have any questions or concerns.

Yours sincerely,

Patric Amcoff
Principal administrator
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Cc: European Commission (DGs Environment, Enterprise, Sanco, Science, JRC, ECVAM)
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